

REMARKS

This paper responds to the Office Action mailed August 8, 2005 (the "Office Action"). Claims 1-8, 15-20 and 55-86 are pending.¹ In the Office Action, the Examiner has withdrawn Claims 73-86 from consideration.

Claims 1, 6, 7, 8, 18, 63, 66, 70 and 73 are amended in this response. The amendments to Claims 7, 8, 66 and 70 correct a typographical error. The amendments to Claims 1, 6, 18, 63 and 73 result from the limiting of Y to $N(R^{12})S(O)_m$, as discussed further below.² Claims 1, 63 and 73 have also been amended to specifically recite pharmaceutically acceptable salts of the compounds; support for amendments to these claims can be found in the specification at, e.g., page 7, line 33 – page 8, line 34. No new matter has been introduced by the amendments.

I. The Restriction Requirement

The Examiner has restricted the subject matter of the pending claims into two groups, Group I (Claims 1-8, 15-20 and 55-72) drawn to compounds and compositions, and Group II (Claims 73-86) drawn to methods of treatment. The Examiner has withdrawn Claims 73-86 from consideration because they were not originally presented.

Applicant hereby confirms election of the subject matter of Group I. Applicant respectfully traverses the restriction on the basis that the search and examination of the subject matter in both Groups I and II would not impose an undue burden on the Examiner, as Group I is drawn to compounds and compositions and Group II is drawn to methods of use involving compounds of the scope claimed in Group I.

Should the subject matter of Group I be allowable, Applicant respectfully requests the Examiner consider the subject matter of Group II for rejoinder.³ [MPEP 821.04].

¹ The Office Action states that Claims 1-20 and 55-86 are pending. The Examiner correctly indicated that Claims 21-54 were previously cancelled, and Applicant points out that Claims 9-14 were also cancelled in the Amendment filed on or about May 9, 2005.

² Applicant notes that reference in the Office Action to Y being " $N(R^{11})S(O)_x$ " should have been to " $N(R^{12})S(O)_m$ ", and Applicant's Remarks hereafter reflect the correction.

³ So that the scope of the method of use claims comports with that of the compound and composition claims, withdrawn Claim 73 has been amended in a manner analogous to that in the compound and composition claims.

II. The Rejection of Claims 1-8, 15-20 and 55-72 under 35 U.S.C. § 112, Second Paragraph, Should be Withdrawn

Claims 1-8, 15-20 and 55-72 stand rejected under 35 U.S.C. § 112, second paragraph. In particular, the Examiner asserts that other than compounds where $X = S(O)_k$ and $Y = N(R^{12})S(O)_m$, "the specification does not enable the ordinary artisan to make or use the instant compounds." [Office Action, p. 3]. Without acquiescing to the propriety of the rejection as it pertains to possible Y-substituents other than $N(R^{12})S(O)_m$, and solely to expedite prosecution, Applicant has amended the claims to indicate that Y is limited to $N(R^{12})S(O)_m$. Applicant respectfully traverses the rejection as it pertains to possible X substituents other than $X = S(O)_k$.

A. The Legal Standard

To satisfy 35 U.S.C. § 112, first paragraph, a specification must, *inter alia*, describe a claimed invention sufficiently to enable one of ordinary skill in the art to practice the invention without undue experimentation. *See In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The multi-factor test summarized by the Federal Circuit in *Wands* forms the basis for an inquiry into whether an amount of experimentation is undue.

The *Wands* factors include (1) the quantity of experimentation necessary, (2) the amount of guidance provided, (3) the presence or absence of working examples, (4) the nature of the invention, (5), the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *See id.* The test for determining whether experimentation is undue is "not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine or the specification provides a reasonable amount of guidance with respect to ... the experimentation." *See Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982).

Finally, the PTO must establish a *prima facie* case of non-enablement in order to properly reject a claim on that basis. "When rejecting a claim under the enablement requirement of § 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention in the specification of the application..." *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). The PTO's *prima facie* case should address each of the *Wands* factors since "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the [*Wands*] factors while ignoring one or more of the others." *See* MPEP § 2164.01(a), citing *Wands* at 1407.

B. Substituents for X where X = S(O)_k are Enabled

Initially, Applicant respectfully asserts that the PTO failed to establish a *prima facie* case of non-enablement, as the PTO focused on only one of the *Wands* factors - the presence or absence of working examples. *See* MPEP § 2164.01. Regardless, Applicant contends that even focusing solely on this factor, albeit improperly, results in a finding that the claims as amended are, in fact, enabled. Consideration of the other *Wands* factors solidifies that contention.

The specification discloses numerous examples where X is a substituent other than S(O)_k. To illustrate, several examples are set forth where X = O when Ar¹ is either phenyl (*see, e.g.*, Examples 26-33) or naphthyl (*see, e.g.*, Examples 56-57). Similarly, the specification includes several examples where X = -C(O)- or (C₁-C₆)alkylene when Ar¹ is phenyl (*see, e.g.*, Examples 59-61).

Examples of other possible substituents for the X variable are included in the specification when Ar¹ is a moiety other than phenyl or naphthyl. By way of example, the specification discloses compounds where X = -N(R¹¹)- (*see, e.g.*, Examples 75 and 209-216); Applicant contends that the skilled artisan would be able to use chemical methods similar to those described in these examples to synthesize compounds where Ar¹ is phenyl or naphthyl. Furthermore, the extensive guidance provided in the specification, including numerous working examples, and the relatively high skill of those in the art, among other *Wands* factors, supports Applicant's assertion that the claims are, indeed, enabled.

For at least the reasons set forth above, Applicant's specification, coupled with the level of skill in the art, enables a person of skill in the art to make and/or use the claimed invention. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph, as lacking enablement.

III. The Rejection of Claims 1-8, 15-20 and 55-72 under the Judicially-Created Doctrine of Obviousness-Type Double Patenting Should be Withdrawn

Claims 1-8, 15-20 and 55-72 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly obvious variants of Claims 1-33 of U.S. Patent No. 6,620,827 ("the '827 Patent").

In response, Applicant respectfully submits that no claim of the '827 Patent provides motivation to select the specific subgenus of compounds recited by Claims 1-8, 15-20 and

55-72⁴. As such, the ordinarily-skilled artisan would not regard the subject matter of Claims 1-8, 15-20 and 55-72 as obvious variants of any claim of the '827 Patent.

B. The Legal Standard

Under the judicially-created doctrine of obviousness-type double patenting, a claim must be patentably distinct from a *claim* of an already issued patent or pending application. See *General Food Corp. v. Studiengesellschaft Kohle mbH*, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992; emphasis added). If the claim at issue defines more than an obvious variation of the patented or pending claim, it is patentably distinct and rejection of the claim under the doctrine of obviousness-type double patenting is improper. *Id.* To establish a proper obviousness-type double patenting rejection, the Examiner must show that the claim at issue is a "mere variation" of the patented or pending claim that "would have been obvious to those of ordinary skill in the relevant art." See *In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986). In the analysis, the "patent disclosure may not be used as prior art;" instead, the Examiner must focus on the "subject matter that *has been protected*, not...something one may find to be disclosed by reading them" or the specification. See *General Food Corp.*, 23 U.S.P.Q.2d at 1846, quoting *In re Vogel*, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970) and *In re Boylan*, 157 U.S.P.Q. 370, 371 (C.C.P.A. 1968).

Moreover, a proper obviousness-type double patenting analysis parallels the obviousness analysis performed under 35 U.S.C. § 103(a). See *In re Braat*, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991) and M.P.E.P. § 804. Thus, arguments showing non-obviousness under 35 U.S.C. 103(a) may be made to show that a claim is not an obvious variant of a patented or pending claim. For example, Applicants may show that the claims at issue are not obvious variants of the patented claims by showing that such claims are not *prima facie* obvious variants of the patented claims. One way Applicants may show such non-obviousness is to show that the patented claims define a genus that does not suggest the species or subgenus recited by the claims at issue. See *In re Baird*, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994).

⁴ Applicant notes that Claims 1-8, 15-20 and 55-62 relate to a particular genus of compounds, while Claims 63-72 relate to compositions comprising such compounds. Therefore, the compositions of Claims 63-72 encompass the genus of compounds recited by Claims 1-8, 15-20 and 55-62, and thus Applicants address all of the claims together.

**C. No Claim of the '827 Patent Suggests Selection
of the Compounds of Claims 1-8, 15-20 and 55-72**

The Examiner stated that "[t]he claims of the ['827] patent are fully encompassed by the instant claims." [Office Action, p. 4]. As discussed further below, Applicant respectfully disagrees. Moreover, none of the claims of the '827 Patent suggest the compounds recited by Claims 1-8, 15-20 and 55-72, as none of the '827 Patent's claims provides the specific motivation needed to select the particular substituents recited by Claims 1-8, 15-20 and 55-72.

The '827 Patent's claims do not encompass all of the subject matter of Claims 1-8, 15-20 and 55-72. By way of example, R³ is halogen, cyano, nitro or (C₁-C₈)alkoxy in the instant claims. In contrast, none of the '827 Patent's claims allow R³ to be any substituent other than hydrogen. Applicant respectfully reminds the PTO that the specification of the '827 Patent disclosure cannot be used to construct the obviousness-type double patenting rejection. Rather, only the *claims* of the '827 Patent can be used in this analysis. The '827 Patent's claims neither recite possible substituents at the position corresponding to R³ of the pending claims nor provide any motivation to select the particular substituents necessary to construct the particular subgenus recited by the instant claims.

In view of this absence of suggestion or motivation, the PTO cannot establish that Claims 1-8, 15-20 and 55-72 are *prima facie* obvious variants of the claims of the '827 Patent.

CONCLUSION

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned at 650/244-2105.

Applicant believes that no fee is due in connection with this response beyond the fees associated with the Petition for Extension of Time. Should an additional fee be required, the Commissioner is hereby authorized to charge any such required fee(s) to Deposit Account No. 01-0519.

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Respectfully submitted,



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